Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 31D1038213	**(X3) Date Survey Completed** 10/27/2021
Name of Provider or Supplier Warren Skin Care Center	**Street Address, City, State** 755 Memorial Parkway, Phillipsburg, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on surveyor observation of the Staining Station (SS) where Mohs testing was performed and interview with the Testing Personnel (TP), the laboratory failed to minimize contamination of reagents, from 1/17/19 to the date of the survey. The findings include: 1. Observation of the SS revealed the laboratory did not maintain the SS to prevent contamination of reagents. 2. The TP confirmed on 10/27/21 at 10:10 am the SS was not maintained to minimize contamination.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

	(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP) the laboratory failed to have all applicable procedures for Histopathology tests from 1/17/19 to the date of the survey. The finding includes: 1. The laboratory did not have a procedure for slide retention. 2. The TP confirmed on 10 /27/2021 at 10:15 am that the PM did not have all applicable procedures.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Staining Station and interview with the Testing Personnel (TP), the laboratory failed to label the identity of all staining jars used for Histopathology testing from 1/17/19 to the date of the survey. The TP confirmed on 10 /27/21 at 10:35 am that all staining jars were not labeled.